

### **REMARKS**

Applicants respectfully request entry of amendments to claims 32, 33, 39, 41, 43, 47, 50, 51, and 53. Please cancel claims 1-31, 38, 46, and 52, and withdraw claims 40, 42, 44, 45, 48, 49, and 54, without prejudice or disclaimer. Support for the amendments can be found throughout the specification, including p. 6, ll. 18-20, p. 13, l. 18 bridging to p. 14, l. 18, p. 18, l. 25 bridging to p. 20, l. 2, Examples XI, XII, XIII, and Figures 4 and 5, and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 32-37, 39, 41, 43, 47, 50, 51, and 53 are in condition for allowance, or are in better condition for presentation on appeal, and respectfully request that the claims as amended be entered.

### **Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 50 and 51 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

Regarding claim 50, while Applicants do not acquiesce to the reasoning offered in the Office Action, in order to expedite prosecution toward allowance, the claim has been amended to recite “the synoviocytes are fibroblast-like synoviocytes present in synovial tissue.” As claim 50 is ultimately dependent from claim 32, where claim 50 further defines the synoviocytes of claim 32 by reciting that they are “fibroblast-like synoviocytes,” the antecedent basis issue is moot.

Regarding claim 51, while Applicants do not acquiesce to the reasoning offered in the Office Action, in order to expedite prosecution toward allowance, claim 47 has been amended to recite the vectors in the alternative, and claim 50 has been amended to recite AAV only. As such, there is not conflict between the claims.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

**Rejection Under 35 U.S.C. §112, First Paragraph**

Claim 52 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description support. As claim 52 has been canceled, the rejection as applied to this claim is rendered moot.

For this reason, Applicants respectfully request that the rejection be withdrawn.

**Rejection Under 35 U.S.C. §102**

Claims 32-37, 39, 41, 43, 46, 47, 50, 51 and 53 stand rejected under 35 U.S.C. §102(e), as allegedly being anticipated by Roth et al. As claim 46 has been canceled, the rejection as applied to this claim is rendered moot.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that Roth et al. teach a composition that anticipates the claimed invention. Claim 32 has been amended to recite the following:

A composition comprising a nucleic acid encoding a polypeptide that promotes apoptosis in mammalian cells,  
wherein the composition comprises transfected synoviocytes containing a DNA vector encoding wild-type p53,  
wherein the synoviocytes express mutant p53 protein, and  
wherein the composition is within a joint of a mammalian subject.

Roth et al. do not teach or suggest synoviocytes, synoviocytes comprising mutant p53, or synoviocytes within a joint of a mammalian subject having rheumatoid arthritis. Thus, the cited reference does not teach a composition comprising the cells as recited and a nucleic acid vector encoding wild-type p53.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

Therefore, because the instant claims recite a composition comprising a nucleic acid encoding p53 and synoviocytes, which composition is not taught or suggested in Roth et al., the reference does not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

In re Application of:  
Gary S. Firestein et al.  
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Page 9

PATENT  
Attorney Docket No. UCSD1160-4

**Conclusion**

Applicants submit that pending claims 32-37, 39, 41, 43, 47, 50, 51, and 53 are in condition for allowance, or are in better condition for appeal. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fee is deemed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees required by this submission, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number.

Respectfully submitted,

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